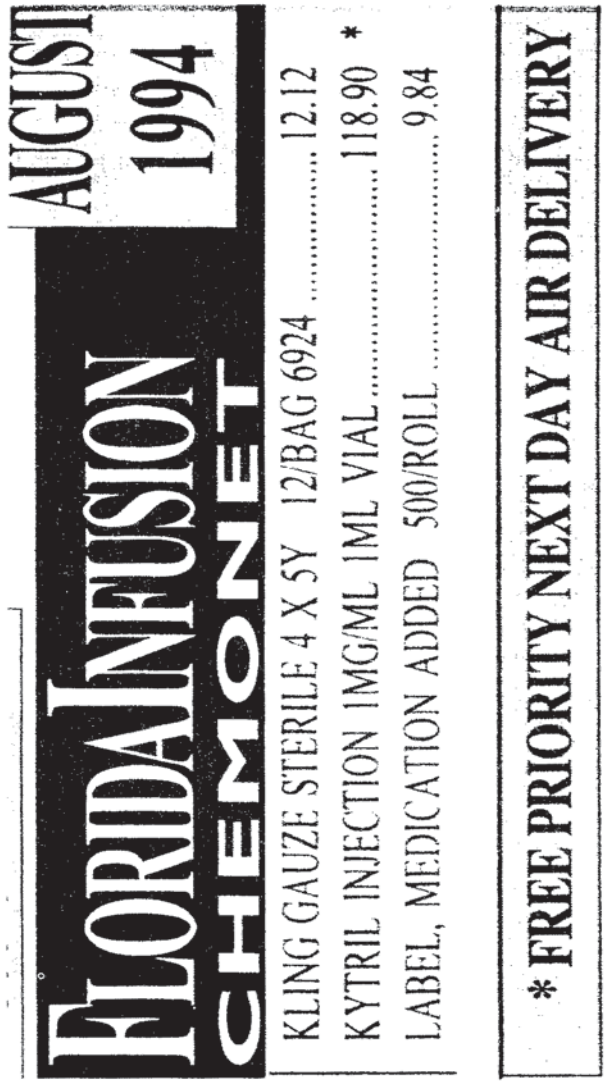
ANDERSON EXHIBIT 10I


FLORIDA INFUSION
CHEMONET
AUGUST
1994
KLING GAUZE STERILE 4 X 5Y 12/BAG 6924 ..... 12.12
KYTRIL INJECTION 1MG/ML 1ML VIAL ..... 118.90 *
LABEL, MEDICATION ADDED 500/ROLL 9.84
* FREE PRIORITY NEXT DAY AIR DELIVERY

U-3

1-800-624-0152
FLORIDA INFUSION CHEMONET
OCTOBER 1994
ZOFRAN®
2mg/mL 20mL
172.92*
16945*
For Case of 40 Vials
KYTRIL®
1mg/mL 1mL
LOWEST PRICE EVER IN THE PHYSICIAN MARKET
11275
For 30 Vials or more
1mg/mL
KYTRIL
GRANISETRON INJECTION
1mL Single-Use
*FOR PHYSICIANS AND CLINICS ONLY
VALID FROM OCTOBER 10 - OCTOBER 31, 1994

KYTRIL™

We have been notified that, effective April 1, 1995, SmithKline's long running promotional rebate for Kytril purchases will come to a very successful conclusion. In anticipation of the impact the loss of this rebate is certain to have, and to encourage you to stock up, we are offering our lowest price ever on Kytril. Order **12** vials or more and take advantage of the sale price of **$111.95**! This offer is valid through February 28, 1995. Once rebates are removed, our best estimate is that prices will rise to **$118** and beyond. Please plan now.

$111.95

12 vials or more

Valid until February 28, 1995

FLORIDA INFUSION

Please fill out the following information for consideration on Texas Medicaid

INCLUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

1.

U-4

DRUG DESCRIPTION

NDC NO: 0088-1206-32 ✓	PACKAGE QTY: 5ml/100mg vial, 1-ct. ✓
(multiple package size of same to be included)	strength products may
PRODUCT BRAND NAME: Anzemet ✓	
GENERIC NAME: dolasetron mesylate	
PRIVATE BRAND NAME: not applicable (if applicable)	
DRUG STRENGTH: 100mg/ 5ml ✓	
COLOR: None ✓	FLAVOR: None ✓
DOSAGE FORM: injectable ✓	IS THIS DRUG LABELED OR OTC? LEGEND ✓
	*ORANGE BOOK RATING: NOT RATED
	DEA SCHEDULE OF THIS DRUG: No

25.47960

PRICE INFORMATION	
AVERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY	$ 149.88 ✓
DIRECT PRICE TO PHARMACY	$ None
PRICE TO WHOLESALER AND/OR DISTRIBUTOR	$ 124.90
SPECIAL PRICE TO CHAIN WAREHOUSE	$ None
SPECIAL PRICE TO INSTITUTIONAL PHARMACY, i.e., (Nursing Home, Home Health Care	$ None
OTHER PRICE	$ None

Attach copies of price lists - one set of price lists is sufficient for multiple submittals.

3. Please circle the companies to whom you report pricing information.

FIRST DATA BANK PRICE ALERT
RED BOOK
MEDI-SPAN
BLUE BOOK
OTHERS: _____

Do you sell to distributors, repackagers, or wholesalers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number? None

If yes, attach a listing.

I certify that the information submitted is correct to the best of my knowledge and that this product is not now in violation of either Federal or State Law. I also agree to inform the Texas Department of Health, in writing, of any changes in formulation, product status, price or availability as herein described, within fifteen (15) days of such change.

Susan D. Zalenski
Responsible Person (Type or Print)

Director, State Government Relations
Title

10236 Marion Park Drive, P. O. Box 9627
Address

Kansas City, MO 64137
City State Zip

Roechst Marion Roussel, Inc.
Company Name

(816) 966-3137
Telephone

Signature

Now Available!

Anzemet™

A New 5-HT_3 Receptor Antagonist

(dolasetron mesylate injection/tablets)
from Hoechst Marion Roussel

ONCOLOGY THERAPEUTICS NETWORK

Excellent Efficacy and Safety Profile

Great Value!

CATALOG NUMBER	NDC	BRAND NAME	ITEM	UNIT SIZE	ORDER QUANTITY	PRICE/ UNIT	AWP
970-250	0088-1206-32	Anzemet	dolasetron mesylate	100 mg vial	1	$70.00	$149.88
970-300	0088-1203-05	Anzemet	dolasetron mesylate	100 mg tablets	5	$289.75	$1340.00
970-305	0088-1203-29	Anzemet	dolasetron mesylate	100 mg tablets blister pack	5	$289.75	$330.00
970-310	0088-1203-43	Anzemet	dolasetron mesylate	100 mg tablets unit dose	10	$579.50	$660.00

U-5

Outstanding Support:

Reimbursement and Patient Assistance Program Hotline 1-888-895-2219

Call the Anzemet Hotline for help with reimbursement and patient assistance programs, Monday through Friday between 10:00 am and 6:00 pm ET.

Call OTN today at 1-800-482-6700 to place your order!

V

TOPIC: QUESTION ADDRESSING THE CONSERVATIVE NATURE OF THE GAO ESTIMATES OF PROFITS FROM THESE DRUGS.

Mr. Bentley, the spreads or profits noted in the IG and GAO testimony are quite significant. I understand that these profits are based on prices that are available to Ven-a-Care, which is a very small home infusion pharmacy. Is that correct? For larger concerns, such as U.S. Oncology, I assume those buyers could get even better prices, resulting in more profits for the provider and a larger expense for Medicare and the beneficiary.

How many providers in the health care industry can buy many of these drugs at the price US Oncology is able to negotiate and how many at the price Venacare is able to negotiate. In your opinion, how conservative are the IG and GAO estimates for the overcharging to the Medicare sytem?

Vol 2. 1

ONE HUNDRED SEVENTH CONGRESS

U.S. House of Representatives

Committee on Energy and Commerce

Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 5, 2001

Mr. Charles Rice
Chief Executive Office
Dey Laboratories
2751 Napa Valley Corporate Drive
Napa, CA 94558

Dear Mr. Rice:

As you know, the House Energy and Commerce Committee has been conducting an exhaustive investigation into the issue of the pricing of Medicare-covered drugs over the past several years. In furtherance of its principal goal of protecting the Medicare program and its beneficiaries from unnecessarily inflated costs for Medicare-covered drugs, the Committee intends to hold a hearing on September 12, 2001, before its Subcommittees on Health and Oversight and Investigations, to further explore how the abuses in the current system can be eliminated.

We understand that Committee staff recently extended an invitation for you to testify at this hearing. We further understand that this invitation was declined, based upon concerns relating to the ongoing investigation being conducted by the Texas Attorney General's office. While we fully appreciate these concerns, we would urge you to reconsider this decision. It is imperative for the Subcommittees to hear from drug manufacturers about their pricing practices under the current Medicare reimbursement system, which result in significant "spreads" between the reimbursement price and the actual price paid by providers for these drugs. This type of abuse is costing the taxpayers, the Medicare system, and Medicare beneficiaries hundreds of millions of dollars every year, and must be stopped.

We sincerely hope that you will reconsider this request, and agree to testify at the hearing on September 12th. Please respond in writing to this request no later than close of business on Friday, September 7, 2001, and if you should choose to decline to testify, please provide your reasons for doing so. If you should have any questions regarding this matter, please contact Charles Clapton, Committee counsel, at (202) 226-2424.

Sincerely,

Michael Bilirakis
Chairman
Subcommittee on Health

James Greenwood
Chairman
Subcommittee on Oversight
& Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John Dingell, Ranking Member
The Honorable Sherrod Brown, Ranking Member, Subcommittee on Health
The Honorable Peter Deutsch, Ranking Member, Subcommittee on Oversight & Investigations

ONE HUNDRED SEVENTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 5, 2001

Wolfgang Plischke
President, North America
Bayer Corporation, Pharmaceuticals Division
400 Morgan Lane
West Haven, CT 06516

Dear Mr. Plischke:

As you know, the House Energy and Commerce Committee has been conducting an exhaustive investigation into the issue of the pricing of Medicare-covered drugs over the past several years. In furtherance of its principal goal of protecting the Medicare program and its beneficiaries from unnecessarily inflated costs for Medicare-covered drugs, the Committee intends to hold a hearing on September 12, 2001, before its Subcommittees on Health and Oversight and Investigations, to further explore how the abuses in the current system can be eliminated.

We understand that Committee staff recently extended an invitation for you to testify at this hearing. We further understand that this invitation was declined, based upon concerns relating to the recent recall of Baycol and the demands that this has placed upon your staff. While we fully appreciate these concerns, we would urge you to reconsider this decision. It is imperative for the Subcommittees to hear from drug manufacturers about their pricing practices under the current Medicare reimbursement system, which result in significant "spreads" between the reimbursement price and the actual price paid by providers for these drugs. This type of abuse is costing both the taxpayers, the Medicare system and Medicare beneficiaries hundreds of millions of dollars every year, and must be stopped.

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Sincerely,

Michael Bilirakis
Chairman
Subcommittee on Health

James Greenwood
Chairman
Subcommittee on Oversight
& Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John Dingell, Ranking Member
The Honorable Sherrod Brown, Ranking Member, Subcommittee on Health
The Honorable Peter Deutsch, Ranking Member, Subcommittee on Oversight & Investigations

ONE HUNDRED SEVENTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

September 5, 2001

Miles White
Chairman and CEO
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

Dear Mr. White:

As you know, the House Energy and Commerce Committee has been conducting an exhaustive investigation into the issue of the pricing of Medicare-covered drugs over the past several years. In furtherance of its principal goal of protecting the Medicare program and its beneficiaries from unnecessarily inflated costs for Medicare-covered drugs, the Committee intends to hold a hearing on September 12, 2001, before its Subcommittees on Health and Oversight and Investigations, to further explore how the abuses in the current system can be eliminated.

We understand that Committee staff recently extended an invitation for you to testify at this hearing. We further understand that this invitation was declined. Given the important role that drug manufacturers play in the current reimbursement system for Medicare-covered drugs, we would urge you to reconsider this decision. It is imperative for the Subcommittees to hear from drug manufacturers about their pricing practices under the current Medicare reimbursement system, which result in significant "spreads" between the reimbursement price and the actual price paid by providers for these drugs. This type of abuse is costing the taxpayers, the Medicare system, and Medicare beneficiaries hundreds of millions of dollars every year, and must be stopped.

We sincerely hope that you will reconsider this request, and agree to testify at the hearing on September 12th. Please respond in writing to this request no later than close of business on Friday, September 7, 2001, and if you should choose to decline to testify, please provide you reasons for doing so. If you should have any questions regarding this matter, please contact Charles Clapton, Committee counsel, at (202) 226-2424.

Sincerely,

Michael Bilirakis
Chairman
Subcommittee on Health

James Greenwood
Chairman
Subcommittee on Oversight
& Investigations

cc: The Honorable W.J. "Billy" Tauzin, Chairman
The Honorable John Dingell, Ranking Member
The Honorable Sherrod Brown, Ranking Member, Subcommittee on Health
The Honorable Peter Deutsch, Ranking Member, Subcommittee on Oversight & Investigations

ABBOTT

Mark E. Barmak
Vice President, Government Affairs

Abbott Laboratories
Dept. 0386 - R3D
100 Abbott Park Road
Abbott Park, IL 60064-6035

Telephone 847 937 8213
Facsimile 847 937 8565

September 7, 2001

VIA FACSIMILE--(202) 226-2447

The Honorable Michael Bilirakis and The Honorable James Greenwood
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Bilirakis and Greenwood.

Since Mr. White is out of the country, he has requested that I respond to your letter dated September 5, 2001. After careful review of this matter, we have reconsidered our position declining your invitation to appear at the September 12 hearing.

As you may be aware, at the request of Congressman Greenwood, I visited with him and members of the Subcommittee staff to discuss this issue. While we commend the Committee for its efforts, we do not believe that we would be able to provide any real insights that would be of value to the Committee. For this reason we respectfully decline your invitation to testify at the hearing.

Sincerely,

Mark E. Barmak

MEB:jm

Bayer

Pharmaceutical
Division

Mark A. Ryan
Vice President
Public Policy & Communications

The Honorable James C. Greenwood, M.C.
United States House of Representatives
Chairman, Subcommittee on Oversight and Investigations
2436 Rayburn House Office Building
Washington, DC 20515

September 7, 2001

Dear Chairman Greenwood:

I have just recently received your invitation to Dr. Plischke, President of Bayer Pharmaceutical North America, to appear before the House of Representatives Subcommittee on Health and the Subcommittee on Oversight and Investigations hearing on "Medicare Drug Reimbursement" scheduled for September 12, 2001. This is a subject that we at Bayer have spent many hours examining and consider to be of great importance to the patients using our products, as well as to third-party payers, such as the federal government.

To meet a special request of the Oversight and Investigations Subcommittee, Dr. Plischke re-routed his trip from Japan to make a personal visit with you concerning these issues on June 6th, 2001. As you may know, Bayer has entered into an agreement with the Department of Justice and is currently adhering to a "Corporate Compliance Program" relating to just this issue. This information is public knowledge and discloses the way in which we price our products.

Since then Bayer Pharmaceutical has voluntarily withdrawn Baycol ®, our cholesterol-lowering agent. This withdrawal of one of our company's leading products has required all the resources of our company, and will for the near future. Dr. Plischke is currently not in the United States and is also unavailable for the September 12th hearing. I have asked our legal counsel in Washington DC, Paul Kalb of Sidley Austin Brown & Wood, to furnish your committee with our Corporate Compliance Program and information relating to the Department of Justice and State agreements.

On behalf of Bayer Pharmaceutical and Dr. Plischke, I hope this will further your committee examination of this important issue. Please know that we all commend your untiring efforts to improve the health and well-being of our citizens.

Sincerely,

Mark A. Ryan

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone 203 812-8439
Fax 203 812-3017
mark.a.ryan.b@bayer.com

Sep-10-01 09:18am From-Coudert Brothers T-481 P.001/002 F-514

DEY, L.P.
2751 Napa Valley Corporate Drive
Napa CA 94558
TEL (707) 224-3200 FAX (707) 224-3335

September 10, 2001

The Honorable Michael Bilirakis
The Honorable James Greenwood
Committee on Commerce
Subcommittee on Health
Subcommittee on Investigations and Oversight
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Bilirakis and Greenwood:

After careful consideration and much deliberation, I must respectfully decline your invitation to appear before the joint Energy and Commerce Subcommittees on Investigations and Oversight, and Health at this time. Appearing as the only pharmaceutical manufacturer puts me in a position to appear to be speaking on behalf of the entire pharmaceutical industry, something I would never presume to do.

As I have indicated, should you assemble a panel of pharmaceutical manufacturers to discuss the reimbursement issue in the future, I will participate.

I continue to offer my knowledge and time to the efforts of the Committee to draft legislative improvements to current pharmaceutical reimbursement policies. To that end, I offer you and the Committee my thoughts, which I hope will help you in your deliberations.

In my judgment, any legislative improvements must consider the following:

1. **Critical terms need to be defined by statute so all participants can be assured that they are fully complying with the law.**
2. **Reimbursement policy must adequately consider the costs imposed on each participant in the value chain for prescription drugs.**
3. **There should be a level playing field that encourages and promotes competition.**

To the first point, Average Wholesale Price (AWP) has never been defined by statute. Dating back more than 20 years, there are public reports, investigations, studies, court and administrative rulings, recommendations from HHS, and Presidential pronouncements, confirming that AWP is not a "true" price. While the industry, regulators and public officials have understood this, some are now asserting that a different meaning exists. Without terms defined in statute, controversy will persist.

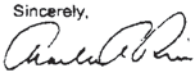
Second, adequate patient care involves numerous stakeholders including researchers, manufacturers, distributors, dispensers, prescribers and service providers. In total, all of these constitute the value chain for prescription drugs, each legitimately seeking appropriate compensation for its services. If prescription drugs were reimbursed merely at or slightly above acquisition cost, that would disregard the value contributed by non-manufacturers to the care of patients. This could result in inadequate provision of care and ultimately higher costs to the government and the patient.

Third, piecemeal changes can steer decisions in the wrong direction. Some attempted solutions, while well intended, can be more costly than anything found in the current system. As an example, the proposed "quick fix" last year to change the reimbursement for 50 pharmaceutical products, which Congress rightly suspended, is an example of an action that disregards the importance of competition as well as the value chain. This type of selective restriction forces the market to higher priced products, which would have immediately created an un-level playing field and increased costs to the government.

In closing I believe there would be much to gain by getting all the stakeholders together with officials at HHS to discuss and propose solutions. To our knowledge, no such effort has been undertaken to date. I also think it would be helpful to hear from non-government payers on their methods of handling reimbursement issues.

I commend your efforts at tackling these issues and remain committed to assist you and the Committee.

Sincerely,



Charles A. Rice
President & CEO

Bayer

Pharmaceutical Division

Mark A. Ryan
Vice President
Public Policy & Communications

The Honorable Michael Bilirakis, M.C.
United States House of Representatives
Chairman, Subcommittee on Health
2269 Rayburn House Office Building
Washington, DC 20515

September 7, 2001

Dear Chairman Bilirakis:

I have just recently received your invitation to Dr. Plischke, President of Bayer Pharmaceutical North America, to appear before the House of Representatives Subcommittee on Health and the Subcommittee on Oversight and Investigations hearing on "Medicare Drug Reimbursement" scheduled for September 12, 2001. This is a subject that we at Bayer have spent many hours examining and consider to be of great importance to the patients using our products, as well as to third-party payers, such as the federal government.

To meet a special request of the Oversight and Investigations Subcommittee, Dr. Plischke re-routed his trip from Japan to make a personal visit with Chairman Greenwood concerning these issues on June 6, 2001. As you may know, Bayer has entered into an agreement with the Department of Justice and is currently adhering to a "Corporate Compliance Program" relating to just this issue. This information is public knowledge and discloses the way in which we price our products.

As widely reported in the press, Bayer Pharmaceutical has very recently voluntarily withdrawn Baycol ®, our cholesterol-lowering agent. This withdrawal of one of our company's leading products has required all the resources of our company, and will for the near future. Dr. Plischke is currently not in the United States and is also unavailable would for the September 12th hearing. I have asked our legal counsel in Washington DC, Paul Kalb of Sidley Austin Brown & Wood, to furnish your committee with our Corporate Compliance Program and information relating to the Department of Justice and State agreements.

On behalf of Bayer Pharmaceutical and Dr. Plischke, I hope this will further your committee examination of this important issue. Please know that we all commend your untiring efforts to improve the health and well-being of our citizens.

Sincerely,

Mark A. Ryan

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone 203 812-5439
Fax 203 812-3017
mark-a ryan 5@bayer com

Vol. 2.
2

Medicare Payments for Prescription Drugs

Response to Request from
Representative W. J. Tauzin

June 2001

OEI-03-01-00490

U.S. Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 20 2001

The Honorable W. J. Tauzin
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Tauzin:

In response to your request, we are providing you with information on the amount of beneficiary coinsurance that would be saved if Medicare drug payments were based on prices available to other sources. In this report, we compared Medicare prices for 24 drugs to Department of Veterans Affairs prices and to wholesale catalog prices. We have enclosed four tables which illustrate the impact excessive payment amounts have on the Medicare program and its beneficiaries.

This report provides data clearly demonstrating that Medicare pays too much for prescription drugs. For example, we found that Medicare would save $1.9 billion a year if 24 drugs were reimbursed at prices available to the Department of Veterans Affairs. Over $380 million of this savings would directly impact Medicare beneficiaries in the form of reduced coinsurance payments. In some cases, the Department of Veterans Affairs price for a drug was less than the amount a Medicare beneficiary would pay in coinsurance. More conservatively, Medicare and its beneficiaries would save $887 million a year by paying the actual wholesale prices available to physicians and suppliers for these 24 drugs. Beneficiaries would pay over $175 million less in coinsurance if Medicare paid for these drugs based on catalog prices.

The majority of the data in this report was first presented in our September 2000 report, "Medicare Reimbursement of Prescription Drugs," (OEI-03-00-00310). The pricing data was collected in the second quarter of 2000 from Medicare carriers, the Department of Veterans Affairs, and several wholesale pricing catalogs. In order to provide a current estimate of potential savings, we have updated the total Medicare allowed charges data from the figures which appeared in the original report.

If you have any questions about this report, or if we can provide further assistance, please call me or George Grob, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Robert Vito at (215) 861-4558.

Sincerely,

Helen Albert
Director, External Affairs

Enclosures

TABLE OF CONTENTS

PAGE

TABLE 1:

MEDICARE AND THE DEPARTMENT OF VETERANS AFFAIRS
UNIT COSTS AND BENEFICIARY COINSURANCE

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		VA PRICE AS PERCENTAGE OF MEDICARE PRICE	20% MEDICARE COINSURANCE	
		MEDICARE	VA		CURRENT	BASED ON VA PRICE
J0640	Leucovorin Calcium, 50 mg	$18.02	$1.63	9.0%	$3.60	$0.33
J1260	Dolasetron Mesylate, 10 mg	$14.82	$4.95	33.4%	$2.96	$0.99
J1440	Filgrastim, 300 mcg	$171.38	$130.72	76.3%	$34.28	$26.14
J1441	Filgrastim, 480 mcg	$273.03	$208.23	76.3%	$54.61	$41.65
J1562	Immune Globulin, 5g	$396.63	$110.54	27.9%	$79.33	$22.11
J1626	Granisetron HCl, 100 mcg	$18.54	$7.81	42.1%	$3.71	$1.56
J2405	Ondansetron HCl, 1 mg	$6.09	$3.94	64.7%	$1.22	$0.79
J2430	Pamidronate Disodium, 30	$243.56	$203.45	83.5%	$48.71	$40.69
J2820	Sargramostim, 50 mcg	$27.41	$10.06	36.7%	$5.48	$2.01
J7608	Acetylcysteine, per g	$5.05	$1.50	29.7%	$1.01	$0.30
J7619	Albuterol Sulfate, per mg	$0.47	$0.07	14.9%	$0.09	$0.01
J7644	Ipratropium Bromide, per mg	$3.34	$0.84	25.2%	$0.67	$0.17
J9000	Doxorubicin HCl, 10 mg	$42.92	$6.29	14.7%	$8.58	$1.26
J9045	Carboplatin, 50 mg	$101.37	$41.14	40.6%	$20.27	$8.23
J9170	Docetaxel, 20 mg	$283.65	$151.77	53.5%	$56.73	$30.35
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.86	84.6%	$17.69	$14.97
J9202	Goserelin Acetate, 3.6 mg	$446.49	$214.87	48.1%	$89.30	$42.97
J9206	Irinotecan, 20 mg	$117.81	$75.45	64.0%	$23.56	$15.09
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$257.00	43.4%	$118.52	$51.40
J9265	Paclitaxel, 30 mg	$173.49	$107.59	62.0%	$34.70	$21.52
J9310	Rituximab, 100 mg	$420.29	$239.58	57.0%	$84.06	$47.92
J9350	Topotecan, 4 mg	$573.75	$307.25	53.6%	$114.75	$61.45
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$46.20	61.2%	$15.10	$9.24
Q0136	Epoetin Alfa, per 1000 units	$11.40	$7.22	63.3%	$2.28	$1.44

TABLE 2:

MEDICARE AND THE DEPARTMENT OF VETERANS AFFAIRS
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		PERCENT SAVINGS	2000 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	VA			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$1.63	91.0%	$69,228,203	$50,372,930	$12,593,232	$62,966,162
J1260	Dolasetron Mesylate, 10 mg	$14.82	$4.95	66.6%	$82,482,309	$43,946,040	$10,986,510	$54,932,550
J1440	Filgrastim, 300 mcg	$171.38	$130.72	23.7%	$51,133,657	$9,705,191	$2,426,298	$12,131,488
J1441	Filgrastim, 480 mcg	$273.03	$208.23	23.7%	$83,837,285	$15,918,122	$3,979,531	$19,897,653
J1562	Immune Globulin, 5g	$396.63	$110.54	72.1%	$49,903,101	$28,796,164	$7,199,041	$35,995,205
J1626	Granisetron HCl, 100 mcg	$18.54	$7.81	57.9%	$42,674,561	$19,758,276	$4,939,569	$24,697,845
J2405	Ondansetron HCl, 1 mg	$6.09	$3.94	35.3%	$55,003,100	$15,534,537	$3,883,634	$19,418,172
J2430	Pamidronate Disodium, 30 mg	$243.56	$203.45	16.5%	$156,095,768	$20,564,957	$5,141,239	$25,706,197
J2820	Sargramostim, 50 mcg	$27.41	$10.06	63.3%	$27,758,142	$14,056,294	$3,514,073	$17,570,367
J7608	Acetylcysteine, per g	$5.05	$1.50	70.3%	$22,452,105	$12,626,530	$3,156,633	$15,783,163
J7619	Albuterol Sulfate, per mg	$0.47	$0.07	85.1%	$261,270,168	$177,886,072	$44,471,518	$222,357,590
J7644	Ipratropium Bromide, per mg	$3.34	$0.84	74.9%	$310,310,047	$185,814,399	$46,453,600	$232,267,999
J9000	Doxorubicin HCl, 10 mg	$42.92	$6.29	85.3%	$30,586,166	$20,882,969	$5,220,742	$26,103,711
J9045	Carboplatin, 50 mg	$101.37	$41.14	59.4%	$140,046,625	$66,568,083	$16,642,021	$83,210,104
J9170	Docetaxel, 20 mg	$283.65	$151.77	46.5%	$110,792,891	$41,209,565	$10,302,391	$51,511,957
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.86	15.4%	$100,322,242	$12,338,978	$3,084,744	$15,423,722
J9202	Goserelin Acetate, 3.6 mg	$446.49	$214.87	51.9%	$375,955,270	$156,023,668	$39,005,917	$195,029,586
J9206	Irinotecan, 20 mg	$117.81	$75.45	36.0%	$117,789,971	$33,882,239	$8,470,560	$42,352,798
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$257.00	56.6%	$633,720,145	$287,109,660	$71,777,415	$358,887,075
J9265	Paclitaxel, 30 mg	$173.49	$107.59	38.0%	$284,530,532	$86,462,906	$21,615,727	$108,078,633
J9310	Rituximab, 100 mg	$420.29	$239.58	43.0%	$135,054,269	$46,454,890	$11,613,722	$58,068,612
J9350	Topotecan, 4 mg	$573.75	$307.25	46.4%	$34,885,298	$12,963,042	$3,240,761	$16,203,803
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$46.20	38.8%	$27,866,679	$8,651,589	$2,162,897	$10,814,486
Q0136	Epoetin Alfa, per 1000 units	$11.40	$7.22	36.7%	$536,916,452	$157,495,493	$39,373,873	$196,869,366
TOTAL FOR 24 DRUGS					$3,740,614,986	$1,525,022,594	$381,255,648	$1,906,278,242

TABLE 3:

MEDICARE AND WHOLESALE CATALOGS
UNIT COSTS AND BENEFICIARY COINSURANCE

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		CATALOG PRICE AS PERCENTAGE OF MEDICARE PRICE	20% MEDICARE COINSURANCE	
		MEDICARE	CATALOGS		CURRENT	BASED ON CATALOG PRICE
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	16.3%	$3.60	$0.59
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	55.9%	$2.96	$1.66
J1440	Filgrastim, 300 mcg	$171.38	$144.30	84.2%	$34.28	$28.86
J1441	Filgrastim, 480 mcg	$273.03	$229.90	84.2%	$54.61	$45.98
J1562	Immune Globulin, 5g	$396.63	$300.00	75.6%	$79.33	$60.00
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	74.5%	$3.71	$2.76
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	90.1%	$1.22	$1.10
J2430	Pamidronate Disodium, 30	$243.56	$223.26	91.7%	$48.71	$44.65
J2820	Sargramostim, 50 mcg	$27.41	$23.13	84.4%	$5.48	$4.63
J7608	Acetylcysteine, per g	$5.05	$3.38	66.9%	$1.01	$0.68
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	27.7%	$0.09	$0.03
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	45.8%	$0.67	$0.31
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	23.5%	$8.58	$2.02
J9045	Carboplatin, 50 mg	$101.37	$87.79	86.6%	$20.27	$17.56
J9170	Docetaxel, 20 mg	$283.65	$238.86	84.2%	$56.73	$47.77
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	84.2%	$17.69	$14.90
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	84.2%	$89.30	$75.20
J9206	Irinotecan, 20 mg	$117.81	$98.63	83.7%	$23.56	$19.73
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	84.2%	$118.52	$99.81
J9265	Paclitaxel, 30 mg	$173.49	$146.10	84.2%	$34.70	$29.22
J9310	Rituximab, 100 mg	$420.29	$353.93	84.2%	$84.06	$70.79
J9350	Topotecan, 4 mg	$573.75	$507.32	88.4%	$114.75	$101.46
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	84.9%	$15.10	$12.82
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	94.0%	$2.28	$2.14

TABLE 4:

MEDICARE AND WHOLESALE CATALOGS:
POTENTIAL MEDICARE AND BENEFICIARY SAVINGS

HCPCS CODE	GENERIC DRUG NAME	2000 MEDIAN PRICES		PERCENT SAVINGS	2000 ALLOWED CHARGES	POTENTIAL SAVINGS		
		MEDICARE	CATALOGS			MEDICARE	BENEFICIARY	TOTAL
J0640	Leucovorin Calcium, 50 mg	$18.02	$2.94	83.7%	$69,228,203	$46,346,784	$11,586,696	$57,933,480
J1260	Dolasetron Mesylate, 10 mg	$14.82	$8.29	44.1%	$82,482,309	$29,074,736	$7,268,684	$36,343,420
J1440	Filgrastim, 300 mcg	$171.38	$144.30	15.8%	$51,133,657	$6,463,762	$1,615,941	$8,079,703
J1441	Filgrastim, 480 mcg	$273.03	$229.90	15.8%	$83,837,285	$10,594,886	$2,648,721	$13,243,607
J1562	Immune Globulin, 5g	$396.63	$300.00	24.4%	$49,903,101	$9,726,217	$2,431,554	$12,157,771
J1626	Granisetron HCl, 100 mcg	$18.54	$13.81	25.5%	$42,674,561	$8,709,846	$2,177,461	$10,887,307
J2405	Ondansetron HCl, 1 mg	$6.09	$5.49	9.9%	$55,003,100	$4,335,220	$1,083,805	$5,419,025
J2430	Pamidronate Disodium, 30 mg	$243.56	$223.26	8.3%	$156,095,768	$10,408,094	$2,602,023	$13,010,117
J2820	Sargramostim, 50 mcg	$27.41	$23.13	15.6%	$27,758,142	$3,467,489	$866,872	$4,334,361
J7608	Acetylcysteine, per g	$5.05	$3.38	33.1%	$22,452,105	$5,939,804	$1,484,951	$7,424,756
J7619	Albuterol Sulfate, per mg	$0.47	$0.13	72.3%	$261,270,168	$151,203,161	$37,800,790	$189,003,951
J7644	Ipratropium Bromide, per mg	$3.34	$1.53	54.2%	$310,310,047	$134,529,625	$33,632,406	$168,162,031
J9000	Doxorubicin HCl, 10 mg	$42.92	$10.08	76.5%	$30,586,166	$18,722,268	$4,680,567	$23,402,835
J9045	Carboplatin, 50 mg	$101.37	$87.79	13.4%	$140,046,625	$15,009,041	$3,752,260	$18,761,302
J9170	Docetaxel, 20 mg	$283.65	$238.86	15.8%	$110,792,891	$13,995,878	$3,498,970	$17,494,848
J9201	Gemcitabine HCl, 200 mg	$88.46	$74.49	15.8%	$100,322,242	$12,674,671	$3,168,668	$15,843,338
J9202	Goserelin Acetate, 3.6 mg	$446.49	$375.99	15.8%	$375,955,270	$47,490,150	$11,872,538	$59,362,688
J9206	Irinotecan, 20 mg	$117.81	$98.63	16.3%	$117,789,971	$15,341,391	$3,835,348	$19,176,739
J9217	Leuprolide Acetate, 7.5 mg	$592.60	$499.03	15.8%	$633,720,145	$80,050,211	$20,012,553	$100,062,764
J9265	Paclitaxel, 30 mg	$173.49	$146.10	15.8%	$284,530,532	$35,936,556	$8,984,139	$44,920,694
J9310	Rituximab, 100 mg	$420.29	$353.93	15.8%	$135,054,269	$17,059,081	$4,264,770	$21,323,851
J9350	Topotecan, 4 mg	$573.75	$507.32	11.6%	$34,885,298	$3,231,275	$807,819	$4,039,094
J9390	Vinorelbine Tartrate, 10 mg	$75.50	$64.11	15.1%	$27,866,679	$3,363,194	$840,799	$4,203,993
Q0136	Epoetin Alfa, per 1000 units	$11.40	$10.72	6.0%	$536,916,452	$25,621,276	$6,405,319	$32,026,595
TOTAL FOR 24 DRUGS					$3,740,614,986	$709,294,617	$177,323,654	$886,618,271

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Memorandum August 31, 2001

TO: House Committee on Energy and Commerce
Attention: Charles M. Clapton

FROM: Thomas J. Nicola
Legislative Attorney
American Law Division

SUBJECT: Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price

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This memorandum responds to a request for a regulatory and legislative history of Medicare drug reimbursement based on the average wholesale price (AWP) of the drug. An AWP is fixed by publishers based on information submitted by drug manufacturers, suppliers, and distributors. The AWP is printed in the wholesale price guides, *Drug Topics Red Book*, *Price Alert*, and *Medispan*.

Although Medicare generally does not pay for prescription drugs under Part B, Supplemental Insurance Benefits for the Aged and Disabled, it does pay for drugs and biologicals that cannot be self-administered, as determined by regulations, and furnished as an incident to a physician's professional service and commonly either rendered without charge or included in the physician's bill. Section 1861(s)(2) of the Social Security Act, 42 U.S.C. 1395x(s)(2). These are sometimes referred to as "incident to" drugs and biologicals and consist of those that are furnished by injection or infusion, including chemotherapy agents. (Generally, this discussion will use the term "drugs" to encompass both "drugs and biologicals.") Until 1992, some carriers reportedly based payment for these agents on the physician's estimated cost of the drug using a wholesale price guide such as the *Red Book*, while other carriers based payment on actual acquisition costs determined on the basis of carrier surveys[1]. 58 *Fed. Reg.* 25800 (June 5, 1991).

Since the beginning of the Medicare program in 1965, Medicare policy had been to base payment on incident to drugs on the estimated acquisition costs, what was called the "reasonable charge" system. *Id.* In June of 1991, in a notice of proposed rulemaking of a

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[1] Prior to 1992, carriers' use of the *Red Book* and other wholesale price guides as sources of average wholesale prices appears to have been based on the Medicare Carriers Manual, part 3, section 5202, which referred to them. Use of carrier surveys appears to have been impeded by the Office of Management and Budget in response to a Paperwork Reduction Act petition. Telephone conversation with Robert Niemann, Center for Medicare and Medicaid Services (Sept. 4, 2001).

fee schedule for services of physicians, the Health Care Financing Administration, now the Center for Medicare and Medicaid Services, decided not to include these drugs in a fee schedule, but rather to make a separate payment for each drug and require carriers to use a consistent method of payment. *Id.*

The notice indicated that some studies by the Office of Inspector General of the Department of Health and Human Services investigating the Medicaid program had led HCFA to believe that the *Red Book* and other wholesale price guides "substantially overstate the true cost of drugs." *Id.*[2] According to these studies, pharmacies were getting an average discount of 15.9% off the published wholesale price and HCFA had no reason to believe that physicians paid higher prices than pharmacies paid. *Id.* The agency proposed instructing carriers to base payment for incident to drugs on 85% of the national average wholesale price (as published in the *Red Book* and similar price listings). For very high volume drugs, HCFA proposed limiting payment to the lower of the estimated acquisition cost for the drug as determined by HCFA and specified in instructions to carriers, or 85% of the national average wholesale price of the drug. *Id.* The proposed regulation for payment of incident to drugs appeared at section 415.34 of title 42 of the Code of Federal Regulations. *Id.* at 25801. *See id.* at 25860 for the text of the proposed regulation.

HCFA proposed this payment policy under authority of section 1842(b)(8) of the Social Security Act, 42 U.S.C. § 1395u(b)(8), which authorizes it by regulation to establish a limit on a charge based on inherent reasonableness if it has determined that a charge is grossly excessive. *See* 42 C.F.R. § 405.502(g)(1)(vi). 56 *Fed. Reg.* at 25800.

In the notice of final rules published in November of 1991, HCFA modified its proposed policy of basing payment for drugs on 85% of the national AWP of the drug and for high volume drugs on the lower of the estimated actual acquisition costs as determined by HCFA and specified in instructions to carriers, or 85 percent of the national AWP. Instead of 85% of the average wholesale price, HCFA decided to base payment for these drugs on the lower of the national AWP, *i.e.*, 100% of AWP, or the Medicare carrier's estimate of actual acquisition costs. 56 *Fed. Reg.* 59525 (Nov. 25, 1991). HCFA published the final regulation at 42 C.F.R. §§ 415.36 (Payment for drugs incident to a physician's service) and 405.517 (Payment for drugs and biologicals that are not paid on a cost or prospective payment basis). *Id. See id.* at 59627 and 59621, respectively, for the texts of the final regulations.

HCFA explained that because there can be many wholesale prices listed for each drug from multiple sources, it defined the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians or other providers, as appropriate, actually pay for the drugs. For certain types of drugs, such as chemotherapy drugs, significant indirect costs such as inventory costs, waste, and spoilage could be considered by carriers if those costs were documented. *Id.* at 59525

HCFA elaborated that many comments, primarily from oncologists, submitted in response to the proposed regulation indicated that the 85% of AWP standard was

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[2] *See* State of Louisiana v. United States Department of Health and Human Services, 905 F.2d 877 (5th Cir. 1990), which affirmed HCFA's denial of a state request to use the AWP for Medicaid reimbursement on the ground that it exceeded estimated actual costs, for a discussion of the widespread state use of the AWP as a primary or significant measure of the estimated acquisition cost prior to this denial and the Inspector General's audit of six states.

inappropriate. Commenters observed that many drugs, particularly multisource drugs, could be purchased for considerably less than 85% of AWP, while others were not discounted. Other commenters suggested that while pharmacies and large medical practices could receive substantial discounts on their drug purchases, individual physicians could not. "The bulk of the comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs." *Id.* at 59524.

Many oncologists suggested that an add-on should be provided in the final regulation to account for the cost of breakage, wastage, shelf-life limitations, and inventory costs associated with chemotherapy agents. Some commenters said that an add-on payment was needed to account for shortfalls in chemotherapy administration payments and that if oncologists did not receive adequate compensation, many physicians would perform the service in hospital outpatient departments at substantially higher costs. Some said that physicians might refuse to supply the drugs to patients, forcing patients to purchase the drugs themselves and bring them to the physician's office to be administered. In the latter case, the drugs would not be covered by Medicare because the physician did not incur any costs for the drugs. *Id.*

Congress revised the reimbursement rate for incident to drugs and biologicals in section 4556 of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 462-463 (1997). Section 4556 amended section 1842 of the Social Security Act, 42 U.S.C. § 1395u, by adding subsection (o).

> (o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part [Part B] and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.
>
> (2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy.

This change was to take effect on January 1, 1998.

Section 4556 also directed the Secretary of Health and Human Services to study the effect of this amendment on the average wholesale price of drugs and biologicals and report to the Committees on Ways and Means and Commerce of the House and the Committee on Finance of the Senate the results of the study not later than July 1, 1999.

The joint explanatory statement said that the conference managers included the House provision, which provided that payment would equal 95% of the average wholesale price, with modifications. The specific modifications were that if payment was made to a licensed pharmacy, the Secretary of Health and Human Services, as the Secretary found appropriate, would pay a dispensing fee (less applicable deductible and coinsurance amounts) and that the Secretary should conduct a study of the effect of the provision on the average wholesale prices and report findings to congressional committees. H. Rep. No. 217, 105th Cong., 1st Sess. 798 (1997).